K110753

DENTSPLY

DENTSPLY International
World Headquarters
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405-0872
(800) 877-0020
Fax (717) 849-4343
www.dentsply.com

JUN - 6 2011

SECTION 5

510(k) SUMMARY
for
MIDWEST® RDH Freedom™ Cordless Prophy System

1.0 Submitter Information

DENTSPLY International
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405

Contact Person: Helen Lewis
Telephone Number: 717-849-4229
Fax Number: 717-849-4343

Date Prepared: 17 March 2011

2.0 Device Name

Proprietary Name:	MIDWEST® RDH Freedom™ Cordless Prophy System
Common Name:	Prophy System
Classification Name:	Handpiece, Direct Drive, AC Powered
CFR Number:	872.4200
Device Class:	I
Product Code:	EKX

3.0 Predicate Device

Zen Cordless Prophy System by Discus Dental, product code EKX, K101612.
Indications for Use – The Zen Cordless Prophy System is a high-performance cordless prophylaxis handpiece with a wireless foot pedal for use with Zen's disposable prophylaxis angles to clean and polish teeth.

K110753

4.0 Description of Device

The MIDWEST® RDH Freedom™ Cordless Prophy System is comprised of a cordless, electric motor-driven handpiece, an AC powered battery charging base and a wireless foot pedal. The handpiece utilizes Freedom disposable prophylaxis angles (single use) that are available with soft cup, hard cup or brush features. The handpiece has been designed for comfort and control by the user. The handpiece has no direct operator controls, and has an internal motion sensing feature which allows it to prepare for operation when the handpiece is picked up. The handpiece can only be operated by the cordless foot pedal, and the amount of vertical displacement on the foot pedal corresponds to the speed of the handpiece. The handpiece is quieter than traditional hygiene and low speed handpieces and features an autoclavable outer sheath for infection control. The MIDWEST® RDH Freedom™ Cordless Prophy System handpiece battery has sufficient power to complete a day's worth of procedures on a single charge, and the system is capable of completing one typical cleaning procedure after only fifteen minutes of charging. The handpiece inner module, the handpiece charger base and the foot pedal are all housed in various plastics. The autoclavable outer sheath is made from aluminum, and the single use disposable prophy angles are made from plastic (and rubber cups).

5.0 Indications for Use

The MIDWEST® RDH Freedom™ Cordless Prophy System is a high-performance cordless prophylaxis handpiece with a wireless foot pedal for use with Freedom disposable prophylaxis angles in a hygiene operatory to perform cleaning and polishing procedures on teeth.

The device is a cordless version of a traditional corded, air powered, low speed handpiece that is used by dental professionals for cleaning and polishing teeth. This system is used in conjunction with prophy pastes or polishes when the procedure is being performed. This is a general hygiene procedure that is performed on people of all ages in a professional dental operatory.

The indications for use of the MIDWEST® RDH Freedom™ Cordless Prophy System and the Zen Cordless Prophy System are essentially the same. They are both cordless, low speed handpieces that are used by a dental professional for cleaning and polishing teeth.

6.0 Identification of Risk Analysis Method

Risk analysis was performed on the MIDWEST® RDH Freedom™ Cordless Prophy System utilizing an FMEA process based on ISO 14971:2007. The results of the risk analysis performed on the MIDWEST® RDH Freedom™ Cordless Prophy System concluded that all device design controls and process controls will be able to mitigate known potential failures and effects. In addition, performance testing, biocompatibility testing and electrical safety and electromagnetic compatibility testing were performed to mitigate other potential risks.

K110753

7.0 Description of Safety and Substantial Equivalence

7.1 Technological Characteristics

The technological characteristics of the MIDWEST® RDH Freedom™ Cordless Prophy System are very similar to the Zen Cordless Prophy System in that they are both cordless devices used for prophylaxis cleaning and powered by a cordless foot pedal. The foot pedal in the MIDWEST® RDH Freedom™ Cordless Prophy System has a Lithium-Ion battery and is able to be recharged multiple times by inclusion of an AC/DC power supply. The foot pedal in the Zen Cordless Prophy System does not have an outside power supply and takes 1.5V AAA batteries which does not allow for the foot pedal battery to be recharged internally. The MIDWEST® RDH Freedom™ Cordless Prophy System and the Zen Cordless Prophy System both have proprietary Disposable Prophy Angles that work exclusively with their own systems. Both systems include removable, autoclavable outer sheaths for infection control. The Zen Prophy System has a handpiece with two options for operation; one is using it with the wireless foot pedal and the other uses a power button located on the handpiece for a constant speed mode. The MIDWEST® RDH Freedom™ Cordless Prophy System has a handpiece that does not have any user interface, and the handpiece is controlled exclusively by the cordless foot pedal. The MIDWEST® RDH Freedom™ Cordless Prophy System and the Zen Prophy System have similar speeds and similar torques, which are well within the range of traditional air-driven hygiene handpieces.

7.2 Non-Clinical Performance Data

Performance testing focused on verification of design, speed, torque, function and safety of the MIDWEST® RDH Freedom™ Cordless Prophy System. The testing included verification of component specifications, speed and torque control, battery life, noise testing, software validation, sterilizability, biocompatibility and electrical equipment safety. Tests were also performed to compare the speed and torque ranges of the MIDWEST® RDH Freedom™ Cordless Prophy System to the Zen Cordless Prophy System to verify substantial equivalence. The results of these performance tests demonstrate that the MIDWEST® RDH Freedom™ Cordless Prophy System is safe and effective for its intended use as a high-performance cordless prophylaxis handpiece with a wireless foot pedal for use with Freedom disposable prophylaxis angles in a hygiene operatory to perform cleaning and polishing procedures on teeth. This testing also verifies that the MIDWEST® RDH Freedom™ Cordless Prophy System is substantially equivalent to the Zen Cordless Prophy System in design, component specifications, speed and torque control, battery life, sterilizability, biocompatibility and electrical equipment safety.

K110753

7.3 Clinical Performance Data

Due to the low risk nature of the MIDWEST® RDH Freedom™ Cordless Prophy System, clinical performance data was not applicable for verification of safety and efficacy.

7.4 Conclusion as to Substantial Equivalence

The similarities in design, function, safety and intended use of the MIDWEST® RDH Freedom™ Cordless Prophy System with the legally marketed device, the Zen Cordless Prophy System, provide evidence that these devices are substantially equivalent. The performance and safety data support the safety and effectiveness of the MIDWEST® RDH Freedom™ Cordless Prophy System for its indicated use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Helen Lewis
Director Corporate Compliance and Regulatory Affairs
Dentsply International, Incorporated
221 West Philadelphia Street, Suite 60
York, Pennsylvania 17404

JUN - 6 2011

Re: K110753
Trade/Device Name: MIDWEST RDH Freedom Cordless System
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EKX
Dated: May 25, 2011
Received: May 26, 2011

Dear Ms. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K110753

Device Name: MIDWEST® RDH Freedom™ Cordless Prophy System

Indications for Use:

The MIDWEST® RDH Freedom™ Cordless Prophy System is a high-performance cordless prophylaxis handpiece with a wireless foot pedal for use with Freedom disposable prophylaxis angles in a hygiene operatory to perform cleaning and polishing procedures on teeth.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110753